

JUN 22 2010

**510(k) Summary of Safety and Effectiveness**

Proprietary Name: Stryker Bipolar Forceps

Common Name: Bipolar Forceps

Classification Name and Reference: Electrosurgical cutting and coagulation device and accessories  
21 CFR §878.4400

Proposed Regulatory Class: Class II

Product Codes: GEI – Electrosurgical cutting and coagulation device and accessories

For Information contact: Rob Yamashita  
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Date Prepared: June 11, 2010

**Description**

The Stryker Leibinger range of Bipolar Forceps contains instruments of various lengths, shapes and sizes.

By means of a suitable bipolar cable, the forceps are connected with the bipolar output of an electrosurgery electrosurgical generator. Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator activated by a footswitch.

In the course of a surgical intervention, bipolar forceps may also be used to grasp and manipulate soft tissue without the activation of the high frequency current.

The Stryker Bipolar Forceps are reusable and provided non-sterile. All forceps must be cleaned and sterilized prior to every use.

#### **Indications for Use / Intended Use**

The Stryker Bipolar Forceps are intended to be used during bipolar electrosurgery to grasp, manipulate and coagulate selected soft tissue. They are connected through a suitable bipolar cable to the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

#### **Contraindications**

The Stryker Bipolar Forceps have not been shown to be effective for tubal ligation or tubal cauterization for sterilization procedures and should not be used for these procedures.

#### **Substantial Equivalence**

The Stryker Bipolar Forceps are substantially equivalent to other commercially available bipolar forceps in regards to intended use, design, materials, and operational principles. The following devices are examples of predicate systems:

- Bipolar Forceps (Stingray Surgical Products Inc., K083162)
- Bipolar Coagulation Forceps (Karl Storz, K960009)
- Non-stick Bipolar Forceps (Silverglide Surgical Technologies, K992931)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Stryker Leibinger Gmbh & Co. Kg  
% Mr. Rob Yamashita  
750 Trade Center Way, Suite 200  
Portage, Michigan 49002

JUN 22 2010

Re: K093108

Trade/Device Name: Stryker Bipolar Forceps  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: June 11, 2010  
Received: June 14, 2010

Dear Mr. Yamashita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

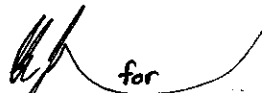
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish extending from the end.

for  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K093108

### Stryker Bipolar Forceps

#### Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K093108